Evolut PRO™ System Clinical Evidence

Excellent Safety Profile

1.7% Mortality

1.7% Disabling Stroke

10% New Permanent Pacemaker

Advanced Sealing

Evolut PRO 30 Day Outcomes

<table>
<thead>
<tr>
<th>None/Trace</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<tbody>
<tr>
<td>27.6%</td>
<td></td>
<td></td>
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<tr>
<td>0%</td>
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Moderate or Severe PVL

Unsurpassed Hemodynamics

Forrest, et al., ACC, 2017
Evolut PRO Clinical Study, 60 patients, 30-day outcomes.
INDICATIONS
The Medtronic CoreValve™ Evolut™ R and CoreValve™ Evolut PRO systems are indicated for use in patients with symptomatic heart disease due to either severe native calcific aortic stenosis or failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (e.g., age >70 years, high surgical risk, or risk of operative death on 30 days).

CONTRAINDICATIONS
The CoreValve Evolut R and CoreValve Evolut PRO systems are contraindicated for patients with any of the following conditions: known hypersensitivity or contraindication to aspirin, heparin (HIT/HITTs) and bivalirudin, ticlopidine, clopidogrel, Nitinol (Titanium or Nickel), or sensitivity to contrast media, which cannot be adequately premedicated; ongoing sepsis, including active endocarditis; and insufficient or nonworking mechanical heart valve in the aortic position.

WARNINGS
General Implications of the CoreValve Evolut R and CoreValve Evolut PRO systems should be provided only to physicians who have received Medtronic CoreValve Training. This procedure should only be performed by a physician who has experience with valve surgery and can perform the procedure. Detailed failure of the delivery catheter system and/or accessories may result in patient complications. Accelerated deterioration of the bioprosthesis may occur in patients presenting with an altered calcium metabolism.

PRECAUTIONS
General
The safety and effectiveness of the bioprosthesis for procedures in the following patient populations: patients who do not meet the criteria for symptomatic severe native aortic stenosis as defined by the systolic gradient of ≥40 mmHg or a symptom-limited maximum aortic velocity ≤4.0 m/s, patients who are at moderate or low surgical risk (predicted operative mortality risk of <15%); with untreated, clinically significant coronary artery disease requiring revascularization; with a pre-existing prosthetic heart valve or vascular prosthetic graft in a bifurcated, radial, or other option; or patients with moderate or severe aortic regurgitation.

Implantation in a degenerative aortic stenosis (TSN stenosis) should be avoided in the following patient populations: patients who are at moderate or low surgical risk (predicted operative mortality risk of <15%); with untreated, clinically significant coronary artery disease requiring revascularization; with a pre-existing prosthetic heart valve or vascular prosthetic graft in a bifurcated, radial, or other option; or patients with moderate or severe aortic regurgitation.

Potential risks associated with the implantation of the CoreValve Evolut R or CoreValve Evolut PRO transcatheter aortic valve may include, but are not limited to, the labeling for proper instruction on the use of balloon catheter devices.

In the retrograde direction. If necessary, and the radiopaque capsule marker band has not yet reached the distal end of the radiopaque paddle attachment, the bioprosthesis can be withdrawn (repositioned) in the retrograde direction. In this case, the radiopaque capsule marker band will reach the distal end of the radiopaque paddle attachment (point of no recapture). If the catheter is withdrawn, the back-up wire should be advanced through the radiopaque capsule marker band before withdrawing the catheter to kink which could increase the risk of vascular complications (for example, vessel dissection or rupture). Persistent force on the catheter can increase the risk of damage to the catheter or kinking which could increase the risk of vascular complications (for example, vessel dissection or rupture). Persistent force on the catheter can increase the risk of damage to the catheter or kinking which could increase the risk of vascular complications (for example, vessel dissection or rupture).

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